Institutional Review Board

North Dakota Department of Human Services

Medical Application for IRB Review of Research Involving the Use of Human Subjects

Type all answers

1. General Personnel Information

Principal Investigator: _____

☐ Non-DHS ☐ DHS Division: _____ Tel#: _____

Fax#: _____

E-mail: _____

Address: _____

Co-Investigator(s): _____

_____

Study coordinator(s), degree(s): _____ Tel#: _____

_____ Fax#: _____

_____ E-mail: _____

2. General Protocol Information

Title: _____

Total project approval period being sought is: From: _____ To: _____

Local number of subjects: _____ ☐ Male ☐ Female Age range: _____

Sponsor/
Funding source: _____

Are you requesting dual enrollment exemption? ☐ Yes ☐ No If yes, list all IRB study numbers with titles for which dual enrollment is being requested. Also, please indicate why dual enrollment with these studies is being requested: _____

_____

_____

_____

Has your project been (or will it be) submitted to another IRB for review?

☐ Yes ☐ No If yes, please complete the following:

Name of IRB	Date Submitted	Status
_____	_____	☐ Approved ☐ Disapproved ☐ Pending
_____	_____	☐ Approved ☐ Disapproved ☐ Pending
_____	_____	☐ Approved ☐ Disapproved ☐ Pending

Proposal #_____

3. Institutions and/or Facilities Used in this Research (Attach Institution approval letter.)

☐ WCHSC	☐ SEHSC	☐ NCHSC	☐ Database (specify):
☐ LRHSC	☐ NEHSC	☐ NWHSC	
☐ BHSC	☐ SCHSC	☐ State Hospital	
		☐ NDDC	☐ Other:

4. Special or Vulnerable Study Subjects Involved in this Research: ☐ **N/A**

(Attach the appropriate informed consent document for each subject population checked)

- ☐ UND Medical Students (Attach approval letter from Medical Student Affairs Committee)
- ☐ UND Medical Residents (Attach approval letter from COM Graduate Medical Education Committee)
- ☐ Pregnant Women ☐ Children ☐ Embryos/fetuses ☐ Juvenile offenders ☐ Prisoners
- ☐ Persons with acute and/or severe mental/physical disabilities ☐ Elderly persons ≥ 65
- ☐ Non-English speaking persons-identify language: _____ (Attach translated consent.)

5. Drugs, Devices, and Procedures ☐ **N/A**

Indicate all of the items that apply to your research.

- ☐ Investigational New Drug—If IND issued, indicate name and no.: _____
- ☐ Investigational New Devices—If IDE issued, indicate name and no.:
  Is this device Significant Risk or Non-Significant Risk? _____
- ☐ FDA approved drug(s) not approved for indication - if IND issued, name, #: _____
- ☐ FDA approved drug(s) ☐ Approved device for new use.
- ☐ Approved procedure that is not approved for indication.

6. Pharmacy and Laboratory Considerations ☐ **N/A**

Will a ***pharmacy*** be used in this study? ☐ Yes ☐ No

If yes, indicate the name and address: _____

If no, where and how will drug(s) be dispensed? _____

Drug administration mode: IV: ☐ IM: ☐ IP: ☐ PO: ☐ SC: ☐ PR: ☐ Other: _____

Please indicate the name(s) and degree(s) of each person who may be administering the drug(s).

_____

_____

Will a ***laboratory*** be used in this study? ☐ Yes ☐ No

☐ central lab ☐ local lab (provide name, address, and laboratory license no.)

_____

_____

7. Radiation Considerations ☐ **N/A**

Approval of Human-Use Radiation Committee: ☐ Pending ☐ Approval date: _____

Approval of Radioactive Drug Research Committee: ☐ Pending ☐ Approval date: _____

8. Genetic Testing Considerations

Will anyone (local or otherwise) be doing any analyses of human genetic material obtained from subjects enrolled in this study? ☐ Yes ☐ No

If the answer to this question is yes, appropriate genetic consent language must be included in the consent form(s) used in this study.

Specify here what you will be testing for:

9. Biosafety Considerations ☐ **N/A**

Does this research involve use of any of the following?

Infectious agents (e.g., hepatitis-causing organisms)?	☐ Yes	☐ No
Regulated toxins (e.g., botulinum toxin)?	☐ Yes	☐ No
Xenotransplantation (cells/tissues/organs from other species into humans)?	☐ Yes	☐ No
Any recombinant DNA technology?	☐ Yes	☐ No
Human Gene Therapy procedures?	☐ Yes	☐ No

If the answer to any of the questions above is yes, this project must be approved by the North Dakota Department of Human Services' Institutional Review Board and have IRB approval before the project can begin. Contact the DHS IRB Chair, Dr. Christine Kuchler, at 1-888-328-2662 for more information.

10. Protocol Design and Subject Specifications

- State either the hypothesis to be tested or the objectives of the proposed research.

- Provide the relevant background pertinent to the hypothesis including the rationale for the experimental procedure, drug, biologic and/or device (limit your answer to 150 words or less).

- Provide a summary of the clinical procedure: standard vs. protocol.

- Describe the source and selection method of the experimental and control subjects. If you are advertising for research subjects, indicate the type of advertising and attach a copy of your advertisement for review. *All advertising must be approved by the IRB before use.*

- Describe the inclusion/exclusion criteria of each subject population.

- Describe the anticipated benefits to subjects in this research.

- Describe the risks and side effects (physical, psychological, and social) to subjects in this research. **List any precautions you are taking to minimize these risks.**

- Describe your consent process: How you will obtain informed consent and how you will ensure confidentiality of the subject.

- List any cost/financial remuneration to the subject as a result of participating in this research.

11. Principal Investigator's Statement of Assurance

The proposed investigation involves the use of human subjects. I am submitting this form with a description of my project prepared in accordance with the North Dakota Department of Human Services' and its affiliates' policies for the protection of human subjects participating in research. I certify that I have either read "The Belmont Report" or viewed the IRB instructional videotapes. I understand the Department's policies concerning research involving human subjects and agree to:

a. Obtain voluntary informed consent of subjects capable of providing consent who are requested to participate in this project;
b. Assure that before human subjects are involved in this project, proper consideration will be given to:
    1. the risks to the subjects
    2. the anticipated benefits to the subjects and others
    3. the importance of the knowledge that may be reasonably expected to result
    4. the need for additional safeguards if the human subjects are especially vulnerable;
c. Report to the IRB any serious or unexpected on-site or off-site adverse events within the appropriate reporting period (Off-site Adverse Event Report or On-site Adverse Event Report);
d. Cooperate with the IRB in the continuing review of this project (Research Progress Reports);
e. Obtain prior approval from the IRB before amending or altering the scope of the project or implementing changes in the approved informed consent form (Change in Procedure Application);
f. Maintain documentation of informed consent forms and progress reports as required by institutional and federal policies;
g. Accept the responsibility for the conduct of this research and the supervision of human subjects as required by law and DHS policies and procedures;
h. Provide a report of the results of the study to the IRB (Research Progress Report);
i. allow the North Dakota Department of Human Services to utilize and disseminate the data I gather and analyze;
j. in the event I am requested to share the data generated by this study at a later time by a *bona fide* researcher, I shall release only data that has either had identifying items deleted or has been encrypted so as to prevent the connection of identity with data.

Signature of Principal Investigator _____ Date _____

12. Signature Requirements

A. Approval of Division Director

_____ _____

Signature of Director Date

Director's name (typed or printed): _____

B. Co-Investigator(s) and Study Personnel Agreement

By this signature, I acknowledge my role in this research study, and will abide by policies of the North Dakota Department of Human Services and its affiliates.

Name	**Degree(s)**	**Role in Study**	**Signature**

To qualify for protocol submission process, you must submit the following:

1. a copy of the research protocol;
2. a copy of any investigator's brochure relating to the protocol.;
3. one copy of the informed consent form(s) for adults, children, or both, as applicable, along with one copy of any necessary informed consent form translations;
4. any documents, certifications, or licensure requested above;
5. if this is a federally funded project you **must** submit a full and complete copy of the appropriate grant application;
6. The original IRB application, the text of any advertisements, physician's letters, affiliate approval letters, etc.

Incomplete submissions *will* be returned without being processed.

Please return this application and any of the above attachments to:

West Central Human Service Center
Attn: DHS IRB Chair
1237 West Divide Ave, STE. 5
Bismarck, ND 58501-1208

Our phone number: 1-888-328-2662

IRB Proposal #_____

FOR IRB USE ONLY:

_____ Full Board Review

_____ Exempt

_____ Expedited Category #

Expedited Review By:

_____
_____
_____

_____ _____
IRB Chairperson Signature Date